

Attorney Docket No. PC10636A
Application No. 09/833,169

Remarks

Applicants gratefully acknowledge the previous allowance of claims 10-12 and 46-48. Applicants' representative would like to thank the Examiner for discussing the subject application with him on April 4, 2006 by telephonic interview. The instant rejection of claims 1-5 and 40-45 and proposed amendments to the claims were discussed during this interview. Particularly, the scope of the claims was discussed and a proposed amendment of certain of the claims by replacement of the term "comprising" with the term "consisting of" was discussed with the Examiner.

Amendments to the Claims

Entry of the above amendments and reconsideration and withdrawal of the rejection of claims 1-5, 40-45 and 50-51 is respectfully requested. Claim 2 has been amended by changing the term "comprising" in the preamble to the term "consisting of" and by addition of the phrase "optionally with a pharmaceutically acceptable vehicle, carrier or diluent." Support for this amendment is in the specification, for example, at page 11, lines 4-11, page 13, lines 18-33 and at page 13, line 18 through page 18, line 2. Claim 4 has been amended by deletion of the term "an optical or geometric isomer thereof." Claim 5 has been amended by addition of the compound name. Support for this amendment is in claim 4, from which claim 5 depends. Claim 40 has been amended by replacing the phrase "and optical or geometric isomers thereof; and pharmaceutically acceptable salts, N-oxides, esters, quaternary ammonium salts, and prodrugs thereof" with the phrase "or an optical or geometric isomer thereof; a pharmaceutically acceptable salt, N-oxide, ester, quaternary ammonium salt, or prodrug thereof." This amendment was done to place the claim in alternative form using the term "or" rather than "and". Claims 42, 43 and 45-46 have been amended by deletion of the term "or an optical or geometric isomer thereof." Claim 44 has been amended by replacing the term "comprising" with the term "consisting of" and by deletion of the term "or an optical or geometric isomer thereof." Claim 49 has been canceled. Claims 52 and 53 have been amended by changing the dependency of these claims from claim 49 to claim 46. Applicants respectfully submit that support for these amendments is in the specification as originally filed and no new matter was introduced by these amendments. If any fees are required for the amendments to the claims please charge those fees to deposit account 16-1445.

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35 U.S.C. § 102(e) Rejection of Claim 1

Claims 1, 2 and 40 have been rejected under 35 U.S.C. 102(e) as allegedly being unpatentable over Place et al. (U.S. Patent 5,877,216 issued March 2, 1999, hereinafter referred to as "Place"). The Examiner has alleged that Place teaches a composition for treating sexual dysfunction and that estrogen antagonists such as tamoxifen, raloxifene and centchroman are disclosed. Applicants respectfully traverse.

Applicants presently claim a method of treating sexual arousal disorder using an estrogen agonist/antagonist, and optionally, a cyclic guanosine 3', 5'-monophosphate elevator. Claims 1, 2 and 40, as amended, recite the term "consisting of" immediately after the preamble of the claim. The "consisting of" language, when used immediately after the preamble of the claim, excludes any element, step or ingredient not specified in the claim (see *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) and MPEP 2111.03. Thus, the present amendment to the claims limits claims 1, 2 and 40 to the specific steps and to the administration of the specific compositions described in those steps.

Place does not teach or disclose the presently claimed method of treating sexual arousal disorder using an estrogen agonist/antagonist, and optionally, a cyclic guanosine 3', 5'-monophosphate elevator and therefore does not anticipate any of claims 1, 2 or 40 as amended.

First, Place does not supply each of the elements of the presently claimed invention. Place discloses the local administration of vasodilating agents to the vagina or vulva. While Place discloses combinations of estrogen agonist/antagonists, Place does not disclose the instant combination of an estrogen agonist/antagonist, and optionally, a cyclic guanosine 3', 5'-monophosphate elevator. Place discloses at column 8, lines 28-30 that "The pharmaceutical formulations used in the methods of the present invention may also include one or more pharmacologically active agents other than the vasodilator." Thus, Place requires that the methods and pharmaceutical compositions disclosed therein must comprise a vasodilator and therefore can not be a method employing an estrogen agonist/antagonist alone. Only in combination with these other compounds is an estrogen agonist/antagonist even mentioned in Place.

Nowhere in Place is a cyclic guanosine 3', 5'-monophosphate elevator mentioned. Further, Place does not disclose the administration of an estrogen

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agonist/antagonist alone to treat sexual arousal disorder. Applicants respectfully submit that Place does not disclose the use of an estrogen agonist/antagonist either alone or in combination with a cyclic guanosine 3', 5' monophosphate elevator to treat sexual arousal disorder in females. Since Place does not disclose the present method of treating sexual arousal disorder by administration of an estrogen agonist/antagonist, either alone or with a cyclic guanosine 3', 5' monophosphate elevator, it thus does not anticipate the presently claimed method. For this reason applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. § 102(e) rejection of claims 1, 2 and 40, as amended.

35 U.S.C. § 103(a) Rejection of Claim 2-4 and 40-44; and Claims 5, 45 and 50-51

Claims 3-4 and 41-44 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Place. Applicants respectfully traverse. Place does not teach or suggest the presently claimed method of treating sexual arousal disorder using an estrogen agonist/antagonist, and optionally, a cyclic guanosine 3', 5'-monophosphate elevator.

Place does not supply the elements of the presently claimed invention, nor does it suggest the presently claimed method. Place is concerned with the local administration of vasodilating agents to the vagina or vulva. Nowhere in Place is a cyclic guanosine 3',5'-monophosphate elevator mentioned. Also, Place does not teach or suggest the administration of an estrogen agonist/antagonist alone to treat sexual arousal disorder. Only in combination with vasodilators is an estrogen agonist/antagonist even mentioned in Place. Moreover, Place does not mention or suggest the particular estrogen agonists/antagonists that are recited in claims 2, 3, 4, 5, 42, 43 or 44.

Last, there is no motivation in Place to arrive at the present method of claims 2-4 and 40-44. Place is concerned only with the local administration of compounds to the vagina or vulva and never mentions administration of an estrogen agonist/antagonist alone and makes no mention of a cyclic guanosine 3',5'-monophosphate elevator at all. Particularly, Place makes no suggestion whatsoever of employing compounds of formula I, formula IA or (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydronaphthalen-2-ol as employed in claims 2-5 and 44. Thus, there can be no suggestion to use an estrogen agonist/antagonist either alone or in combination with an cyclic guanosine 3',5'-monophosphate elevator to treat sexual arousal disorder in females.

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Applicants respectfully submit that Place does not teach or suggest that an estrogen agonist/antagonist either alone or in combination with a cyclic guanosine 3', 5' monophosphate elevator could be used to treat sexual arousal disorder in females. Applicants respectfully request the Examiner to reconsider and withdraw the 35 U.S.C. rejection of claims 2-4 and 40-44.

Claims 5, 45 and 50-51 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Place in view of Chiu et al. Chiu et al discloses the tartrate salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol. Place does not disclose or suggest the use of an estrogen agonist/antagonist either alone or in combination with a cyclic guanosine 3', 5' monophosphate elevator to treat sexual arousal disorder in females as discussed above. Combination of Chiu and Place does not result in nor does it suggest the instantly claimed method. Place teaches the use of certain vasodilators, potentially in combination with other agents to treat female sexual dysfunction. Incorporating the (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol as taught by Chiu into the method of Place results in a method where a vasodilator must be administered optionally with the (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol. This method is not the method as claimed in claims 5, 45 or 50-51. Neither Place nor Chiu provide motivation to one of ordinary skill in the art to modify the method of Place to arrive at the method of instant claims 5, 45 and 50-51 since there is simply no suggestion to do so.

Applicants respectfully assert that Place in view of Chiu does not teach or suggest that (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol, either alone or in combination with a cyclic guanosine 3', 5' monophosphate elevator, could be used to treat sexual arousal disorder in females. Applicants respectfully request the Examiner to reconsider and withdraw the 35 U.S.C. rejection of claims 5, 45 and 50-51, as amended.

Objection to Claims 49 and 52-53

Claim 49 has been canceled thereby rendering the objection to that claim moot. Claims 52-53 have been objected to as being dependent on a rejected base claim. Claims 52-53 have been amended and now depend from claim 46. Claim 46 has been allowed, thus claims 52-53 no longer depend from a rejected base claim.

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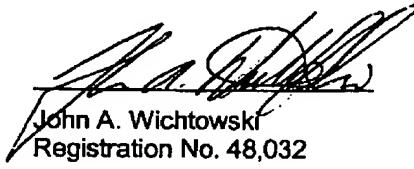
Applicants respectfully request that the Examiner reconsider and withdraw the objection to claims 52-53.

Conclusion

Applicants believe that, in view of the amendments and remarks made above, this application is in condition for allowance. Reconsideration and allowance of claims 1-5, 40-45 and 50-53 is respectfully requested.

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